UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/960,557	10/31/1997	EUGENIO A. CEFALI	50454-56103USCIP	6174

59945 7590 06/14/2007

KOS PHARMACEUTICALS, INC.
1 CEDAR BROOK DRIVE
CRANBURY, NJ 08512-3618

EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
06/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/960,557	CEFALI ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-36 and 38-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-36 and 38-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on *06 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Reciept of amendment and request for continued examination dated 3-21-07 is acknowledged.

Claims 29-36 and 38-61 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3-21-07 has been entered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 29-36 and 38-61 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,080,428; claims 1-148 of U.S. Patent No. 6,129,920; claims 1-30 of U.S. Patent No. 6,469,035; claims 1-16 of U.S. Patent No. 6,406,715, claims 1-21 of U.S. Patent No. 6,746,691, claims 1-28 of U.S. Patent No. 6,818,229 and claims 1-12 of U.S. Patent No. 7,011,848. Although the conflicting claims are not identical, they are not patentably distinct from each other.

Each of the above patents is also directed to the same invention as that claimed in the instant application. Instant claims are directed to a method of treating cholesterol disorders with an intermediate nicotinic acid formulation comprising orally administering once day per day effective in producing a specific dissolution curve similarity fit factor F2.

7011848 also claim the same method as in the instant and with the same active compound. Thus, the claimed dissolution is inherent to the method of the patent because instant claims do not recite any specific chemical composition other than variable dosages of nicotinic acid and a tablet form. Thus, '848 anticipate instant claims.

6818229 claims an intermediate nicotinic acid release formulation, with exactly the same amount (375 mg) of the active agent, claimed in the instant application. While

the claims of the patent are directed to a formulation and not a method, the composition is used for the same purpose as in the instant and it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the composition of the '229 so as to achieve the claimed method of treating hyperlipidemia.

6746691 claim an intermediate nicotinic acid release formulation, with exactly the same amount (375 mg) of the active agent, with an identical dissolution profile including fit Factor, claimed in the instant application. While the claims of the patent are directed to a formulation and not a method, the composition is used for the same purpose as in the instant and it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the composition of the '691 so as to achieve the claimed method of treating hyperlipidemia.

6406715 claims an intermediate nicotinic acid release formulation as claimed in the instant application. While the claims of the patent are directed to a formulation and not a method, the composition is used for the same purpose as in the instant and it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to employ the composition of the '715 so as to achieve the claimed method of treating hyperlipidemia.

6469035 recite a method of releasing nicotinic acid for immediate or extended release during evening or bedtime, in an effective lipid-altering amount. Instant claims

as well as the patented claims require the same active agent i.e., niacin and instant claims do not recite any other component that is different form the patented claims and accordingly the patented formulation inherently result in the instant claimed dissolution. Thus, '035 anticipate instant claims. 6080428 is also directed a method of releasing nicotinic acid for immediate or extended release during evening, similar to '035 and instant claims. Therefore, for the reasons above, '035 also anticipates instant claims.

6129930 claim a method of treating hyperlipidemia with an effective amount of anti-hyperlipidemic nicotinic acid, which is the same method of the instant claims. Instant claims do not recite any specific composition other than the amount of nicotinic acid and a tablet form (dependent claims) and the patented claims recite the amount of nicotinic acid that is within the claimed amounts. Accordingly, the patented composition inherently results in the instant claimed dissolution profile and the fit factor and hence 930 anticipate instant claims.

2. Claims 29-36 and 38-61 are directed to an invention not patentably distinct from the claims 1-13 of U.S. Patent No. 6,080,428; claims 1-148 of U.S. Patent No. 6,129,920; claims 1-30 of U.S. Patent No. 6,469,035; claims 1-16 of U.S. Patent No. 6,406,715, claims 1-21 of U.S. Patent No. 6,746,691, claims 1-28 of U.S. Patent No. 6,818,229 and claims 1-12 of U.S. Patent No. 7,011,848, all of which are commonly assigned, as explained above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned patents, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 29-36 and 38-61 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Instant claims recite a method of treating cholesterol disorders with an intermediate release composition comprising nicotinic acid, which exhibits a specific dissolution profile as claimed. A careful review of the specification only reveals that while instant dissolution profile is achieved with a composition, which is manufactured by wet granulation of hydroxypropyl methylcellulose, povidone and stearic acid. However, instant claims broadly encompass any pharmaceutical delivery system that renders the claimed dissolution, which are not described in the instant application. Accordingly, instant claims fail to meet the written description requirement.

4. Claims 1-5, 17, 19 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating cholesterol disorders with an intermediate release composition comprising nicotinic acid, which exhibits a specific dissolution profile manufactured by wet granulation of hydroxypropyl methylcellulose, povidone and stearic acid, does not reasonably provide enablement for the claimed method with any pharmaceutical delivery system so as to achieve the claimed in vitro dissolution. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01 (a)). These include: breadth of the claims; nature of the invention; state of the prior art; amount of direction provided by the inventor; the level of predictability in the art; the existence of working examples; quantity of experimentation needed to make or use the invention based on the content of the disclosure; and relative skill in the art. All of the factors have been considered with regard to the claim, with the most relevant factors discussed below:

Breadth of the claims & nature of the invention: Instant invention is directed to a method of treating cholesterol disorders with an intermediate release composition comprising nicotinic acid, which exhibits a specific dissolution profile as claimed. Instant claims only recite the active agent and the amount of the active agent (in dependent claims) but not any specific delivery system for the active agent. Thus, the claims broadly recite a composition, without specifying the components or constituents as to how to achieve the claimed profile.

The amount of direction provided by the inventor: A number of delivery systems sustained, controlled, pulse etc., are known in the art for controlled release of drugs or active agents. Applicants admit that immediate and sustained release compositions are known in the art and are designed to release significantly different amounts of drug (pages 2-3). Applicants also describe the disadvantages such as high flush with the above (immediate) release forms and that the design of the SR or IR (sustained or immediate release respectively) has an impact on the release of the drug, such as

hepatic first pass etc., particularly non-linear hepatic first pass. In order to overcome, applicants describe an intermediate release form that provides the claim (page 7). However, a review of the instant specification describes only one formulation i.e., HPMC, povidone and magnesium stearate as a release system to achieve the claimed dissolution and thus the profile. Applicants have not described any other delivery system that can or may achieve (examples) the claimed method. Whereas, instant claims do not recite any specific controlled release system or material and only require "a composition", which is extremely broad and includes any and all possible controlled release material- osmotic, matrix, beads, particles etc. The rate controlling materials are virtually limitless in the art and there is nothing in the specification that equates or correlates that all of the art known release materials are similar and that all of them result in the same in vitro dissolution profiles for nicotinic acid as claimed in the instant application.

In the absence of any guidance regarding other than that described above, a practitioner would turn to trial and error experimentation in testing every known drug delivery material in order to compose a controlled-release oxymorphone composition, with any and all known matrix materials, so as to achieve the claimed profiles. Consequently, a burdensome amount of research would be required by one of ordinary skill in the art, who is presented with a countless number of delivery systems that include water soluble, insoluble polymers, gels, osmotic pumps etc., to arrive at the claimed method.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 29-36 and 38-61 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,268,181 to O'Neil et al (181).

'181 teach a composition comprising niacin in the claimed amounts (see examples), for the treatment of hyperlipidemia (abstract, col. 2). The composition is administered in the evening similar to the instant claims. '181 teaches the same delivery system as that described in the instant claims i.e., HPMC, magnesium stearate etc (see examples). While '181 does not mention the dissolution factors and profiles of instant claims, both '181 and instant claims are directed to the same method of treatment with the same composition and hence the claimed dissolution pattern is inherent to the composition of '181.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 7.00 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AU 1615
June 11, 2007

LAKSHMI S. CHANNAVAJJALA
PRIMARY EXAMINER